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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,143	07/25/2003	Mark S. Spector	N.C. 84,766	3910

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EXAMINER

HANLEY, SUSAN MARIE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 03/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/627,143	<b>Applicant(s)</b> SPECTOR ET AL.	
	<b>Examiner</b> Susan Hanley	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 July 2003.  
 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/25/03</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-26, drawn to a hydrogel, classified in class 524, subclass 916, for example.
- II. Claims 27-33, drawn to a method for assaying biomolecules by linking the biomolecule to the support with a hydrogel, classified in class 435, subclass 40.5, for example.

**\*\*The election of Group I or Group II requires specie elections.**

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case a sugar-based, cross-linked hydrogel can be used as a water soluble polymeric carrier for a drug.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

**If Group I is elected** Applicant is required to make the following specie elections concerning the components of the hydrogel polymer:

A. For the sugar component, Applicant is required to elect one of the following (election of either specie A(i) or specie A(ii) requires further specie elections):

A(i). The sugar compound is an acryl- or methacryl-substituted sugar;

A(ii). The sugar compound has a double bond that is polymerizable but is not an acrylate or methacrylate.

If the acryl- or methacryl-substituted sugar specie A(i) is elected, Applicant is further required to elect one of the following sugar species:

A(i) a. an acryl- or methacryl- monosaccharide;

A(i) b. an acryl- or methacryl- disaccharide

A(i) c. an acryl- or methacryl- oligosaccharide or polysaccharide.

If the sugar compound has a double bond that is polymerizable but is not an acrylate or methacrylate specie A(ii) is elected, Applicant is further required to elect one of the following sugar species:

A(ii) a. a monosaccharide;

A(ii) b. a disaccharide; or

A(ii) c. an oligosaccharide or polysaccharide.

B. For the sugar component, Applicant is required to elect the type of ring structure:

B(i). furanose; or

B(ii). pyranose

The species are independent or distinct because each of the species separately have different structure and chemistry. The combination of elected species makes a monomer that has a different structure and chemistry compared to a monomer from a different set of the possible specie elections.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 3, 4, 10, 12-18, and 21-26 are generic. Claims 2, 4-8, 11, 19, and 20 will be examined insofar as they read on the elected species.

C. For the cross linker component, Applicant is required to elect

C(i). a bis-acrylamide compound;

C(ii). a bis-acrylate compound; or

C(iii). a bis-vinyl compound.

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The species are independent or distinct because each of the species crosslink by different chemistry to produce crosslinked monomers of distinct structure and chemistry.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 4-18, and 21-26 are generic.

Claims 2, 19, and 20 will be examined insofar as they read on the elected claims

D. For the third compound component, Applicant is required to elect if:

D(i). The third compound is a (meth)acrylate; or

D(ii). The third compound is an acrylate.

After electing D(i) or D(ii), Applicant is required to elect if:

a. The polymer backbone comprises amino groups; or

b. The polymer backbone comprises carboxyl groups.

The species are independent or distinct because each of the species provides different functional groups that have different chemistries for linking with compounds or molecules to be grafted to the hydrogel.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-15 are generic. Claims 16-26 will be examined insofar as they read on the elected specie.

E. For the biomolecules linked to the third component, Applicant is required to elect one of the following:

E(i). proteins; or

E(ii). oligonucleotides.

The species are independent or distinct because each of the species has a different function in a living organism.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1, 2, 4-23, and 26 are generic. Claims 3, 24 and 25 will be examined insofar as they read on the elected specie.

If Group II is elected, Applicant is required to elect the following:

A. Applicant is required to elect which hydrogel specie is examined with the method:

A(i). The specie of claim 18; or

A(ii). The specie of claim 19. (Claim 1 is generic to both claims 18 and 19).

The species are independent or distinct because the species of claims 18 and 19 are drawn to a polymer backbone with carboxy groups or amino groups, respectively. The two species represent different functional groups that bond with other molecules by differing chemical reactions.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 27-33 are generic.

B. Applicant is required to elect the type of biomolecule assayed:

B(i). A protein (as in claims 30 and 32); or

B(ii). A DNA molecule (as in claims 28 and 29).

The species are independent or distinct because the proteins and DNA have different functions in a living organisms.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 27, 31 and 33 are generic. Claims 29 and 32 will be examined insofar as they read on the elected species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any

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claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable,

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withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

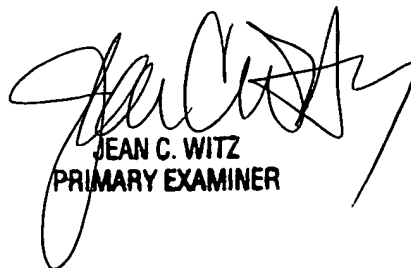
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley  
Patent Examiner  
1651



JEAN C. WITZ  
PRIMARY EXAMINER